



CRYSTAL INTERNATIONAL

January 22, 2004

1901 Camino Vida Roble, Suite 206
Carlsbad, CA 92008-6561 USA
Tel 760 431 0266
800 307 8900
Fax 760 431 0360
info@crystalinternational.com
www.crystalinternational.com

5394 104 JAN 20 10 43

*Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville, MD 20857*

RE: New Bioterrorism Legislation – Docket No. 2002N-0278

This is our second request for information. Below is our letter written to you on December 19, 2003 in its entirety.

To whom it may concern:

As you know, the legislation known as the Public Health Security and Bioterrorism Act of 2002 was recently implemented, effective date December 12, 2003. After reading through much of the information on your website (www.fda.gov/furlis), I am left with some questions and deep concerns as applicable to the industry within which I work, that is the international transport of used household goods and personal effects. Before stating my questions and concerns, I would like to paraphrase some of the new requirements within this new legislation that have a direct impact on my business.

- 1) All parties involved with the manufacture and packaging of foodstuffs must register with the USFDA and have a registration number.
- 2) All unaccompanied shipments imported into the USA that contain food and/or drink for human consumption must be reported to the USFDA prior to their arrival in the USA. The report sent to the USFDA must show, with respect to the foodstuffs only, *Description, Quantity and Units, Company Name and Brand Name, Value, Manufacturers Name and Address, Country of Origin.*

I am the operations manager for Crystal International and, as already mentioned, I work in the international transportation industry, specifically the international transport of used household goods and personal effects. Within this particular arena, my company is intimately involved with the customs clearance and delivery of shipments of wine and alcoholic beverages for US service members "rotating" back to the USA after overseas assignments. The wine and alcoholic beverages in these shipments is being purchased by private individuals, shipped by private individuals, and is intended for consumption by private individuals. The beverages in these shipments are not intended for distribution or resale in the USA. Further, under a program sanctioned by the USDOD, the transportation charges these service members pay on their respective shipments are refunded to them by the US government but duties are charged on all of these shipments and are duly paid by the individual service members.

02N-0278

C292

The wine and alcoholic beverages purchased overseas by the US service members is widely variegated. Herein lays the problem. Descriptions, quantities, units, brand names, and values are readily determined but manufacturer's names and addresses are, many times, not available. Moreover, with the wide variety of wines and beverages purchased comes a wide variety of companies (vintners, brewers, distillers, bottlers, canners, packagers, etc.) that may not be registered with the USFDA and do not intend to do so.

QUESTION: How can these shipments of wines and alcoholic beverages be cleared for entry into the USA?

We have many shipments already in the "pipeline" and obtaining the required information at this point will be virtually impossible. However, it is our understanding that there is a "grace period".

QUESTION: Is there a "grace period"? If so, how long is it?

QUESTION: To what exactly does this "grace period" apply? Information requirements on shipments? Registration with the USFDA?

Further to the above details, the individual shipments of wine/beverages are consolidated and shipped to the USA in containerized lots. There are but a few companies overseas that are involved with the consolidation of these shipments, one of which is HL Van Transport GMBH, located in Niedersachsen, Germany. HL Van has registered with the USFDA and has been issued registration number 10670124940. My company, Crystal International, was listed as HL Van's US agent.

QUESTION: What are the duties, responsibilities, and ramifications of being the agent of a foreign company registered with the USFDA as an entity involved in the shipping of foodstuffs to the USA?

I certainly do understand the need to protect the people of the USA from possible Bioterrorism from intentionally contaminated, poisoned, and/or infected foodstuffs. However, I am concerned that due to the rigidity of this new legislation – which seems to be targeting the wholesale food industry – a large portion of my company's revenue will be lost as we may not be able to clear these shipments through US customs. I would hope that the USFDA would offer some concessions to these rules so that honest, free enterprise will not suffer.

I await your earliest response.

Page 3
USFDA – 2
January 22, 2004

Additionally, I would like to add at this time that, to date, we have had scores of telephone enquiries from service members whose shipments of wine/beverages are stranded in Europe. They have paid for goods that are being denied them due to this new legislation. Please advise what we are to tell them.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Gammuscio', with a long horizontal flourish extending to the right.

*Robert M. Gammuscio
Operations Manager
Crystal International*

*cc: Han Helders, President, Crystal International
Cindi O'Conner, Vice President, Crystal International*